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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,657	02/03/2004	John Nelson	PB0308	4149

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EXAMINER

HORLICK, KENNETH R

ART UNIT PAPER NUMBER

1637

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/770,657	<b>Applicant(s)</b> NELSON, JOHN	
	<b>Examiner</b> Kenneth R. Horlick	<b>Art Unit</b> 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/27/04</u> . | 6) <input type="checkbox"/> Other: ____.  |

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Self-ligation of cDNA to form concatemers or circular products would appear to be a critical feature of the claimed methods.

2. Claims 18-20 are objected to as being duplicates of claims 2-4, respectively. Apparently, dependency of claims 18-20 is intended to be from claim 14.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-24 and 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are confusing because they are drawn to a "process", while independent claims 22 and 25 are drawn to a "method". It is required that these claims be amended for consistency. Further, it cannot be determined what is encompassed by the additional limitation "is used for hybridization analysis" in claims 23 and 26; that is, what exact action(s) would satisfy this language. Clarification is required.

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Kumar et al. (US 6,977,153, filed 12/31/02).

Claims 1-5 are drawn to methods comprising reverse transcribing RNA to form cDNA; self-ligating the cDNA to form concatemers or circular products; and amplifying the ligated cDNA products using random-sequence primers and DNA polymerase.

Claims 6-13 are similar, further including use of a primer comprising an RNA polymerase promoter and the step of transcribing amplified DNA using RNA polymerase. Claims 14-21 are similar, but wherein amplification is via one or more specific primers in isothermal amplification. Claims 22-28 relate to conventional uses of such methods, and claims 29-30 are drawn to kits suitable for use in such methods.

Kumar et al. disclose such methods, further applications for such methods, and kits; see entire document, especially Fig. 1 and columns 2-5, 19-20, and 53.

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6. Claims 1-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lizardi (US 6,124,120).

Lizardi discloses such methods, further applications for such methods, and kits; see entire document, especially Fig. 4 and column 3, lines 29-67; column 4, lines 60-67; column 6, lines 26-34; column 9, line 22 to column 10, line 2; column 12, line 19 to column 13, line 39; column 16, lines 15-49; column 17, lines 24-26; and column 20, line 44 to column 24.

7. Claims 1-5 and 14-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer (US 5,876,932).

Fischer discloses such methods; see entire document, especially column 3, lines 25-39; column 5, lines 14-43; column 9, lines 4-37; and paragraph bridging columns 11 and 12.

8. Claims 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Connor et al. (US 2002/0004592).

Connor et al. disclose such a method; see entire document, especially Fig. 1 and paragraphs 0014, 0018, and 0031-0094.

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9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cleuziat et al. (US 5,849,547).

This claim is drawn to a kit comprising: reverse transcriptase, phi29 DNA polymerase, and RNA polymerase.

Cleuziat et al. disclose a method utilizing these three enzymes, as well as kits comprising reagents suitable for carrying out such a method (see abstract; column 7, lines 18-22; columns 19-20).

While Cleuziat et al. do not explicitly disclose the exact kit of claim 29, one of ordinary skill in the art would have been motivated to make such a kit because it would have clearly been useful in the practice of the method of Cleuziat et al. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed kit.

10. Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quake et al. (US 2002/0164629, effective filing date 03/12/01) in view of Cleuziat et al.

These claims are drawn to a kit comprising: reverse transcriptase, phi29 DNA polymerase, and RNA polymerase; and to such a kit further comprising random sequence amplification primers.

Quake et al. disclose a method utilizing these three enzymes, as well as random primers (see paragraphs 0052 and 0101-0102).

While Quake et al. do not explicitly disclose the exact kit of claims 29-30, one of ordinary skill in the art would have been motivated to make such a kit because it would have clearly been useful in the practice of the method of Quake et al. Cleuziat et al., as noted above, establishes that the use of kits was conventional in the art at the time of the invention. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed kits.


11. No claims are free of the prior art.

12. Hu et al. (US 6,203,984) and Windsor et al. (US 2004/0076966) are made of record as references of interest.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Kenneth R Horlick  
Primary Examiner  
Art Unit 1637

08/16/06